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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,225	03/11/2004	Anand R. Baichwal	540.91195C3CON2	3483

23280 7590 09/15/2005

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,225	BAICHWAL, ANAND R.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *85-97* is/are pending in the application.

4a) Of the above claim(s) *1-3, 6-8, 82-84,* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks field 6/13/05 is acknowledged. Claims **85-97** are pending in this application. Claims 1-3, 6-8, and 82-84 are withdrawn. Claims 4-5 and 9-81 stand cancelled.

Claim Rejections - 35 USC § 112

The rejection of claim 85-88 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the arguments which are found to be persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The rejection of claims 85-86 under 35 U.S.C. 102(b) as being anticipated by Clare et al (4,693,728) are maintained.

Clare et al disclose a hydrocolloid blend for controlled release of calcium ions. Example 1 discloses mixing 250 g hydroxyethyl-guar gum (gelling agent) and 90g calcium citrate (cationic cross linking agent) for five minutes followed by adding water (308g) to form a mixture. The mixture was then dried and milled.

Response to Arguments

Applicant argues that claim 85 has been amended to recite "method of preparing a sustained release excipient *for pharmaceutical use...*" Thus, applicant argues, the Clare patent does not teach a method of preparing a sustained release excipient for pharmaceutical use. Applicant acknowledges that '728 discusses various food- related uses of its hydrocolloid/salt

blends. Applicant argues that '728 is directed to hydrocolloid/salt blends especially useful in alginate print paste compositions.

Applicant's arguments filed 6/13/05 have been fully considered but they are not persuasive. Firstly, the examiner points out that the newly recited phrase "for pharmaceutical use" is a recitation of intended use of the claimed invention. Intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In instant case, the examiner gives weight to the phrase in that the excipient must be non-toxic. The examiner points out that example 1 teaches the hydrocolloid excipient that does not contain any toxic components. Furthermore, Clare discloses the use of the hydrocolloid for pet food and baking goods. Thus, it can be seen that '728 is capable of the recited intended use.

Secondly, the examiner further points out that the instant invention as claimed, i.e. the body of the claim, and the prior art are not structurally distinguishable. Clare discloses the process of making a hydrocolloid blend that comprises instant amount of crosslinking agent and instant amount of gelling agent.

Accordingly, the rejection is maintained.

The rejection of claims 85 and 87-88 under 35 U.S.C. 102(b) as being anticipated by Hotko et al (3,456,049) are maintained.

Hotko et al disclose a gradual release tablet and method of making it. The composition contains an active embedded in a mixture of 5-15% potassium chloride, a fatty substance, 3-15% of alginic acid (gelling agent), and 5-10% of cellulose acetate phthalate. See column 4, lines 70-

75. Hotko discloses passing the active, potassium, sterotex, and alginic acid are mixed. Then cellulose acetate phalate (hydrophobic material) dissolved in alcohol is added and mixed thoroughly. The mixture is then dried, milled, and compressed. See examples, particularly example 7 and 9.

Response to Arguments

Applicant argues that the Hotko patent ('049) is directed to an excipient, which comprises a fatty substance, alginic acid, and a granulating liquid. However, applicant argues that the Hotko patents fails to teach "a pharmaceutically acceptable cationic crosslinking agent capable of cross-linking with said gelling agent when exposed to an environmental fluid to increase the gel strength'" as recited in claims 85 and 87. Further, applicant argues that '049 also fails to teach a pre-manufactured excipient to which a medicament is added, as evidenced by the examples of the Hotko patent, which show all the ingredients, including medicament, mixed together.

Applicant's arguments filed 6/13/05 have been fully considered but they are not persuasive. Firstly, the examiner points out that Hotko discloses examples that utilize potassium chloride or potassium citrate in instant amount, which are known to be crosslinking agents in the art. Prior art to support the examiner's statement is US 5738865 (column 6, lines 44-65) wherein potassium chloride is taught to be a cationic crosslinking agent. US 5679334 (column 3, lines 40-43) is cited wherein potassium citrate is taught to be a cationic crosslinking agent. Note that prior art utilized by the examiner to demonstrate that a component implicitly functions in a certain manner, i.e. that potassium citrate and potassium chloride act as crosslinking agents, can have a post-critical date. See MPEP 2112, Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004). Moreover, the instant disclosure on page 11 teaches

cationic crosslinking agents that may be utilized in the invention include alkali metals and alkaline earth metal. Potassium citrate is an alkali metal.

Secondly with regard to applicant's argument that '049 fails to teach to teach a pre-manufactured excipient, the examiner points out that the instant claim language, i.e. comprising, does not exclude a medicament in the composition.

Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 85-86, 89-93, and 96-97 under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (4,994,276) in view Cohen et al (4,795,642) is maintained.

Baichwal teaches a slow release tablet for oral administration including a heteropolysaccharide (xanthan gum) and a cross-linking agent and a polysaccharide gum (locust bean gum), inert filler (diluent), and an active agent. See column 4, lines 46-55. The ratio of

xanthan gum to locust bean gum is 1:1 and the ratio of the diluent to the gelling agent falls within the recited range of 1:8 to about 8:1. See examples. Polymers such as propylene glycol or hydroxypropylmethylcellulose may be additionally added to the xanthan gum: locust bean gum mixture. See examples 20-28. Baichwal teaches medicaments that are either relatively insoluble or insoluble defined with instant parameters are suitable for the invention. See column 9.

Baichwal et al do not specify the cross linking agent, i.e. cationic.

Cohen et al a gelatin encapsulated controlled release composition. Cohen teaches the use of a cationic gelling agent to "gel" or coagulate the polysaccharide gums yield a polymeric matrix for drug delivery. The polysaccharide gums taught are vegetable gums. The agents taught are compounds such as citrates, phosphates, tartrates, sulfates, borates, chlorides, and the like, of cations such as sodium, lithium, magnesium, and calcium. See column 3, lines 34-51.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings the teachings of Baichwal et al and Cohen et al and include the instant cross linking agents. One would have been motivated to utilize since Cohen et al teach cationic cross liking agents to "gel" the polysaccharide gums to provide for a polymeric matrix for a drug.

Response to Arguments

Applicant argues that Baichwal teaches a pre-manufactured excipient in which medicament is added and compressed into a tablet. Applicant argues that Cohen teaches a gelatin capsule enclosing solid matrix formed by cation-assisted gelation of a liquid fill. Applicant argues that Cohen teaches adding the crosslinking agent to a liquid fill, which already contains a medicament, to form a solid. Applicant argues that the examiner has used improper hindsight.

Lastly, applicant argues that claim 87 recites a hydrophobic material and neither Baichwal nor Cohen teaches a hydrophobic material; thus this rejection is improper.

Applicant's arguments filed 6/13/05 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the examiner points out that the Baichwal patent itself provides a suggestion of utilizing a crosslinking agent. The examiner points to column 4, lines 45-55 wherein Baichwal clearly states: "The present invention also provides a slow release tablet for oral administration comprising (I) a hydrophilic material comprising (a) a heteropolysaccharide; or (b) a heteropolysaccharide and a **cross-linking agent capable of cross-linking said heteropolysaccharide**." The only teaching lacking in Baichwal is a cationic crosslinking agent. Thus, the examiner relies on Cohen who clearly teaches a cationic crosslinking agent to "gel" or coagulate the polysaccharide gums to yield a polymeric matrix for drug delivery. The examiner points out that Baichwal's requirement for the crosslinking agent is that it must be capable of crosslinking the polysaccharide and this requirement is satisfied by Cohen's teachings that the cationic crosslinking agents are capable of crosslinking polysaccharides. Thus, a skilled artisan clearly would reasonably expect success by the instant combination.

With regard to arguments pertaining to Cohen's process of using a liquid polysaccharide and then crosslinking it with a cationic agent to form a solid matrix, it should be noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the examiner is not attempting to import the entirety of Cohen's process into Baichwal's teachings; this is not the premise of the rejection. The premise of the rejection is that the prior art teaches the use of cationic agents to crosslink polysaccharides.

Moreover, if applicant is attempting to argue non-analogous art, the examiner points out that it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Baichwal and Cohen are all directed to controlled release compositions and thus are clearly analogous art.

It is further noted that applicant's arguments are directed against the references *individually*. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner points out that applicant has not argued the combination or provided unexpected results that would overcome the obviousness rejection.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With regard to claim 87, the examiner points out that claim 87 has not been rejected in the above obviousness rejection. Thus, this argument is moot.

Accordingly, the rejection is maintained.

The rejection of claims 87-88 under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (4,994,276) in view Cohen et al (4,795,642), in further view of Hotko et al (3,456,049) is maintained.

As set forth above, Baichwal teaches a method of making a slow release tablet for oral administration including a heteropolysaccharide (xanthan gum) and a cross-linking agent and a polysaccharide gum (locust bean gum), inert filler (diluent), and an active agent. See column 4, lines 46-55. Cohen et al teach the use of a cationic gelling agent to "gel" or coagulate the polysaccharide gums yield a polymeric matrix for drug delivery.

The references do not teach the use of a hydrophobic material as an excipient.

Hotko et al disclose a gradual release tablet and method of making it. Hotko teaches the prior art release tablets wherein a slightly soluble substance is used in the matrices, the release rate is less predictable since the matrices maintain their shape thorough the GI tract; thus they

are excreted without releasing the active agent. Hotko also teaches the use of readily soluble components diffuse too easily causing lesions in the GI tract due to high concentration levels. Thus, the use of a soluble component and an insoluble component allows for release in the intestines. See column 1, lines 29-50. Hotko discloses passing the active, potassium, sterotex, and alginic acid are mixed. Then cellulose acetate phalate dissolved in alcohol (hydrophobic material) is added and mixed thoroughly. The mixture is then dried, milled, and compressed. See examples, particularly example 7 and 9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Baichwal et al and Hotko et al and utilize a hydrophobic material. One would have been motivated to do so since Hotko et al teach the use of a soluble carrier component and an insoluble component provides for a predictable release in the intestines and avoids the disadvantages, such as rapid release, of using only a soluble component.

Response to Arguments

Applicant argues that merits of Baichwal and Cohen respectively and argues that since the examiner has not established prima facie obviousness with regard to Baichwal and Cohen, the instant rejection of Baichwal in view of Cohen in further view of Hotko is also overcome. Applicant argues that Baichwal mentions the Hotko patent in a discussion regarding the shortcomings of the prior art. Applicant cites column 3, lines 8-14 in which Baichwal purportedly discusses Hotko. Thus, applicant argues there a skilled artisan would have not incentive to look to the Hotko patent. Lastly, argues that Hotko describes an excipient, wherein the medicament is mixed directly with excipient ingredients.

Applicant's arguments filed 6/13/05 have been fully considered but they are not persuasive. The merits of Baichwal and Cohen have been addressed above. With regard to Baichwal teaching away from Hotko, the examiner points out that the applicant's arguments are misleading. For instance, applicant cited column 3, lines 8-14 wherein Baichwal teaches away from the Hotko patent. This is an incorrect statement. Baichwal statements pertaining to the Hotko patent are found on column 2 wherein Baichwal states:

> These disclosures concentrate their attention to the type and combination of polymers and/or gums used, and processes for mixing the same, and therefore have not provided a directly compressible form of gums/polymers and adjuvants which can be used for a wide range of medicaments. Other slow release excipients are disclosed in the prior art which are directed to particular therapeutically active medicaments. In one such disclosure, U.S. Pat. No, 3,456,049 (Hotko et al.), a slow release benzothiadiazine diuretic tablets are prepared by mixing a fatty substance such as hydrogenated vegetable oil, alginic acid, a granulating liquid, a potassium salt and the benzothiadiazine. The wet mass is screened, dried, and then compressed into tablets.

Clearly, Baichwal is not teaching away from using a hydrophobic material and rather Baichwal is stating that the prior art fails to teach a compressible form of gums/polymers.

Thus, the examiner motivation to combine the teachings of Hotko still applies. Hotko teaches the use of a soluble carrier component, i.e. a gum, and an insoluble component, i.e. fatty substances, to provide a predictable release in the intestines and avoid the disadvantages of using only a soluble component, such as rapid release. Therefore, a skilled artisan would have been motivated to further add a hydrophobic component to Baichwal's soluble gum component to avoid rapid release.

With regard to Hotko teaching a medicament in the composition, as stated above, the instant claim language does not exclude medicaments in the composition. Moreover, this argument is perplexing since claim 97 is directed to the method of preparing the excipient wherein a gelling agent, a inert diluent, a cationic-crosslinking agent, and **medicament** are combined together.

Accordingly, the rejection is maintained.

The rejection of claims 94-95 under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (4,994,276) in view Cohen et al (4,795,642), in further view of Gulley et al (4,309,405) is maintained.

As set forth above, Baichwal teaches a method of making a slow release tablet for oral administration including a heteropolysaccharide (xanthan gum) and a cross-linking agent and a polysaccharide gum (locust bean gum), inert filler (diluent), and an active agent. See column 4, lines 46-55. Cohen et al teach the use of a cationic gelling agent to "gel" or coagulate the polysaccharide gums yield a polymeric matrix for drug delivery.

The references do not teach an enteric coating for the slow release tablet.

Guley et al teach a sustained release pharmaceutical composition which includes a core containing a drug and a coating. Guley et al teach the use of an enteric coating for protecting the core during its passage from the stomach to the intestine. Enteric coatings are more soluble at a pH greater than 5 (the pH of the intestine). See column 3, lines 15-30. The amount of coating to core is taught on column 3, lines 51-60.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Baichwal et al, Cohen et al, and Guley et al and use an enteric coating for a sustained release compositions. One would have been motivated to do so since Guley teaches enteric coatings protect the drug core during its passage from the stomach to the intestine, thus allowing the composition to release in the intestine rather than the stomach. Therefore, one would have been motivated to use an enteric coating to provide target release of the active to the intestines.

Response to Arguments

Applicant argues the merits of Baichwal and Cohen. Applicant argues that Baichwal does not suggest a seal coating; thus the examiner has used impermissible hindsight reasoning. Applicant argues that Cohen is directed to a liquid fill and Guley is directed to a granulation formulation.

Applicant's arguments filed 6/13/05 have been fully considered but they are not persuasive. The merits of Baichwal and Cohen have been addressed above. Again the examiner notes that the applicant has attacked each reference individually and not the combination itself or more specifically the applicant has not argued the unobviousness of the instant invention.

The examiner further corrects applicant's incorrect statement that Cohen is directed to a liquid fill capsule. Cohen is in fact directed to a solid polymeric matrix in a gelatin capsule. Further, if applicant is attempting to argue non-analogous art, the examiner points out that it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Baichwal, Cohen, and Guley are all directed to controlled release compositions.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In instant case, it was well known at the time the instant invention was made to utilize hydrophobic coatings for targeted release. Therefore, clearly the motivation to use a hydrophobic coating has been known in the pharmaceutical art prior to the instant inventions' filing date and this teaching has not been gleaned from the applicant's disclosure.

Accordingly, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The claims 85-97 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,709,677, US 6,245,356, US 6,048,548, US 5,512,297, US 5,773,025, and provisional application 10/766688 is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim similar subject matter.

Instant claim 85 is directed to the method of preparing a sustained release excipient by dry blending a gelling agent, an inert diluent, and a cationic cross-linking agent.

Instant claim 87 is directed to the method of preparing a sustained release excipient dry blending a gelling agent, an inert diluent, a cationic cross linking agent, and a hydrophobic material.

Instant claim 89 is directed to the method of preparing a sustained release excipient by dry blending a gelling agent, an inert diluent, and a cationic cross linking agent wherein the gelling agent includes a heteropolysaccharide and homopolysaccharide gum in a ratio about 1:3 to about 3:1 and the inert diluent is in a ratio of 1:8 to 8:1.

Instant claim 91 is directed to a method preparing an oral dosage form by dry blending a gelling agent, an inert diluent, a cationic cross linking agent, and a drug wherein the gelling agent includes a heteropolysaccharide and homopolysaccharide gum in a ratio about 1:3 to about 3:1 and the inert diluent is in a ratio of 1:8 to 8:1.

Instant claim 92 is directed to a method preparing an oral dosage form by dry blending a gelling agent, an inert diluent, a cationic cross linking agent, a hydrophobic material, and a drug wherein the gelling agent includes a heteropolysaccharide and homopolysaccharide gum in a ratio about 1:3 to about 3:1 and the inert diluent is in a ratio of 1:8 to 8:1.

Instant claim 93 is directed to a method preparing an oral dosage form by dry blending a xanthan gum and locust bean gum, an inert diluent, a cationic cross linking agent, and a drug wherein the gelling agent includes xanthan gum and locust bean gum in a ratio about 1:3 to about 3:1 and the inert diluent is in a ratio of 1:8 to 8:1.

Instant claim 94 is directed to a method preparing an oral dosage form by dry blending a xanthan gum and locust bean gum, an inert diluent, a cationic cross linking agent, and a drug and coating the tablet with a hydrophobic material.

Instant claim 96 is directed to a method preparing an oral dosage form by dry blending a xanthan gum and locust bean gum, an inert diluent, a cationic cross linking agent, and a drug and coating the tablet with a hydrophobic material wherein the gelling agent includes xanthan gum and locust bean gum in a ratio about 1:3 to about 3:1, the inert diluent is in a ratio of 1:8 to 8:1, and the medicament to gelling agent ratio is 1:3 to 1"8.

Instant claim 97 is directed to the method of preparing a sustained release composition by dry blending a gelling agent, an inert diluent, a cationic cross linking agent, and a medicament.

US patent '677 is directed to a method of preparing a solid dosage form by combining a medicament and a sustained release excipient containing a gelling agent, an enhancing agent (the cationic cross linking agent), ethyl cellulose (hydrophobic material) wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8. Dependent claims are directed to coating the tablet with a hydrophobic coating.

US patent '356 is directed to a method of preparing a solid dosage form by combining a medicament and a sustained release excipient containing a gelling agent, an enhancing agent (the cationic cross linking agent), wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8.

US patent '548 is directed to a method of preparing a solid dosage form by combining a medicament and a sustained release excipient containing a gelling agent, an enhancing agent (the cationic cross linking agent), wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8. Dependent claims are directed to coating the tablet with a hydrophobic coating.

US patent '297 is directed to a method of preparing a solid dosage form by combining a medicament and a sustained release excipient containing a gelling agent, an enhancing agent (the cationic cross linking agent), wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8. Dependent claims are directed to coating the tablet with a hydrophobic coating.

US patent '297 is directed to a method of preparing a solid dosage form by combining a medicament of poor solubility, and a 10-99% sustained release excipient containing a gelling agent, 1-20% an cationic cross linking agent, wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8. Dependent claims are directed to the inclusion of a hydrophobic material (ethyl cellulose).

US patent '025 independent claims 19 and 33 are directed to a method of preparing a solid dosage form by combining a medicament of poor solubility, and a sustained release excipient containing a gelling agent, an enhancing agent (cationic cross linking agent), wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8.

Co-pending application is directed to a method of preparing a sustained release tablet by combining a medicament and a sustained release excipient containing a gelling agent, an enhancing agent (cationic cross linking agent), wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8.

The instant application and the US patents cited above are directed to similar subject matter wherein all the patents and applications are directed a method of making a dosage form containing the critical elements of a gelling agent, a cationic cross linking agent, a drug, and an inert diluent.

With regard to the instant claims directed to a method of making a sustained release excipient with the critical elements of a gelling agent, a cationic cross linking agent, and an inert diluent, this is an obvious modification over the above patents and co-pending application since it is obvious to one of ordinary skill in the art to utilize the sustained excipient with a drug of choice to provide an oral dosage form.

Response to Arguments

Applicant argue that the filing of Terminal Disclaimers will be considered upon notification of allowable subject matter. Accordingly, the rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER